IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

Gordon Dandurand and Margaret R. Dandurand, h/w	:	**COMPLAINT**
Plaintiffs,	:	CIVIL ACTION NO.
v.	:	
Auxilium Pharmaceuticals, Inc.,	:	JURY TRIAL DEMANDED
Defendant.	:	

Plaintiffs, by their attorneys, **ANAPOL SCHWARTZ,** upon information and belief, at all times hereinafter, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendant, as set forth below, is incorporated and has its principal place of business in states other than the state in which the named individual Plaintiffs reside.

2. Venue is proper pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims herein occurred within this district.

PARTIES

3. Plaintiff GORDON DANDURAND was at all relevant times a resident and citizen of Carson, California.

4. Between June 2004 - February 2014, Plaintiff GORDON DANDURAND was prescribed Testim due to low testosterone levels.

5. As a result of his use of Testim, Plaintiff GORDON DANDURAND suffered multiple heart attacks, including but not limited to in August 2010, in February 2012 and/or in December 2012.

6. Plaintiff MARGARET R. DANDURAND was at all relevant times a resident and citizen of Carson, California.

7. At all relevant times, Plaintiff MARGARET R. DANDURAND was and still is the lawful spouse of Plaintiff GORDON DANDURAND.

8. Defendant Auxilium Pharmaceuticals, Inc., is a Delaware corporation which has its principal place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087.

9. At all relevant times Defendant Auxilium Pharmaceuticals, Inc., conducted regular and sustained business in Pennsylvania and California by selling and distributing its products in Pennsylvania and California.

10. Defendant Auxilium Pharmaceuticals, Inc., is sometimes referred to as "Defendant."

FACTUAL ALLEGATIONS

11. Testim is manufactured, sold, distributed and promoted by Defendant as a testosterone replacement therapy.

12. The Defendant misrepresented that Testim is a safe and effective treatment of hypogonadism and a condition sometimes referred to as "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes and thrombolytic events.

13. The Defendant failed to adequately warn physicians about the risks associated with Testim and the monitoring required to ensure patient safety.

14. The Food and Drug Administration approved Testim on October 31, 2002, for the treatment of adult males who have low or no testosterone. After FDA approval, Testim was widely advertised and marketed by Auxilium Pharmaceuticals, Inc., as a safe and effective testosterone replacement therapy.

15. Testim is a hydro-alcoholic gel containing testosterone. Testim is applied to the shoulders and upper arms. Testim enters the body through transdermal absorption.

16. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

17. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

18. In men, testosterone levels normally begin a gradual decline after the age of thirty.

19. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who fall into the hypogonadal range one day will have normal testosterone levels the next.

20. Testosterone products may produce undesirable side effects to patients who use the drugs, including but not limited to, myocardial infarction, stroke and death.

21. In some patient populations, testosterone product use may increase the incidence of myocardial infarctions and death by over 500%.

22. This action is for damages brought on behalf of Plaintiff GORDON DANDURAND who was prescribed and supplied, received and who has taken and applied Testim, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded,

manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendant. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

23. Defendant's wrongful acts, omissions and fraudulent representations caused Plaintiff's injuries and damages.

24. At all relevant times herein mentioned, the Defendant was engaged in the business of, or was successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling of Testim for the use and application by men, including, but not limited to Plaintiff GORDON DANDURAND.

25. At all times herein mentioned, Defendant was authorized to do business within the states of Pennsylvania and California.

26. At all times herein mentioned, the officers and directors of Defendant participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by the Plaintiffs herein.

27. Defendant coordinated a massive advertising campaign designed to convince men that they suffered from low testosterone. Defendant orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone.

28. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness - all general symptoms that are often a result of aging, weight gain or lifestyle, rather than low testosterone.

29. As a result of Defendant's advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions of Testim. If Plaintiff GORDON DANDURAND had known the risks and dangerous associated with Testim, he would not have taken it and consequently would not have been subject to its serious side effects.

FIRST CAUSE OF ACTION
(NEGLIGENCE AND NEGLIGENCE PER SE)

30. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

31. Defendant had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Testim into the stream of commerce, including a duty to assure that its product would not cause users to suffer unreasonable, dangerous side effects.

32. Defendant failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Testim into interstate commerce in that the Defendant knew or should have known that using Testim placed users at risk for developing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms,

cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

33. The negligence of the Defendant, its agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing, producing, promoting, formulating, creating, and/or designing Testim without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing Testim without adequately testing it;

c. Not conducting sufficient testing programs to determine whether or not the aforesaid Testim was safe for use; in that Defendant herein knew or should have known that Testim was unsafe and unfit for use by reason of the dangers to its users;

d. Selling Testim without making proper and sufficient tests to determine the dangers to its users;

e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and/or the FDA of the dangers of Testim;

f. Negligently failing to recall its dangerous and defective Testim at the earliest date that it became known that Testim was, in fact, dangerous and defective;

g. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Testim;

h. Failing to test Testim and/or failing to adequately, sufficiently and properly test Testim;

i. Negligently advertising and recommending the use of the aforesaid Testim without sufficient knowledge as to its dangerous propensities;

j. Negligently representing that Testim is safe for use for its intended purpose, when, in fact, it is unsafe;

k. Negligently representing that Testim has equivalent safety and efficacy as other testosterone replacement products;

l. Negligently designing Testim in a manner which was dangerous to its users;

m. Negligently manufacturing Testim in a manner which was dangerous to its users;

n. Negligently producing Testim in a manner which was dangerous to its users;

o. Negligently assembling Testim in a manner which was dangerous to its users;

p. Concealing information concerning tests, and/or reports, and/or studies from the Plaintiff showing that Testim was unsafe, dangerous, and/or non-conforming with accepted industry standards;

q. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the public, concerning the severity of risks and dangers of Testim; and

r. Defendant violated statutes, rules and ordinates concerning the manufacturing, marketing, and/or testing of its product.

34. Defendant under-reported, underestimated and downplayed the serious danger of Testim.

35. Defendant was negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Testim in that it:

a. Failed to use due care in designing and manufacturing Testim so as to avoid the aforementioned risks to individuals when Testim was used for its intended purpose;

b. Failed to accompany its products with proper warnings regarding all possible adverse side effects concerning the use of Testim;

c. Failed to accompany its products with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Testim;

d. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

e. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Testim;

f. Failed to warn Plaintiff, prior to actively encouraging the sale of Testim, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

g. Were otherwise careless and/or negligent.

36. Despite the fact that Defendant knew or should have known that Testim caused unreasonably dangerous side effects, Defendant continued to market, manufacture, distribute and/or sell Testim to consumers, including the Plaintiff.

37. Defendant's actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence per se.

38. Defendant knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury, and/or be at increased risk of suffering injury as a result of Defendant's failure to exercise ordinary care, as set forth above.

39. Defendant's negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and/or will continue to suffer.

40. By reason of the foregoing Plaintiff GORDON DANDURAND experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

41. As a result of the foregoing acts and omissions, the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

42. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in an amount to be determined at trial.

SECOND CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

43. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

44. At all times herein mentioned, the Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Testim as hereinabove described that was used by Plaintiff.

45. That Testim was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant.

46. At those times, the Testim was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff GORDON DANDURAND.

47. The Testim designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the aforesaid testosterone product.

48. At all times herein mentioned, Testim was in a defective condition and unsafe, and Defendant knew or had reason to know that it was defective and unsafe, especially when used in the form and manner as provided by the Defendant.

49. Defendant knew, or should have known, that at all times herein mentioned its Testim was in a defective condition, and was and is inherently dangerous and unsafe.

50. At the time of the Plaintiff's use of Testim, the aforesaid product was being used for the purposes and in a manner normally intended, namely for the treatment of Low T.

51. Defendant with this knowledge voluntarily manufactured Testim in a dangerous condition for use by the public, and in particular the Plaintiff GORDON DANDURAND.

52. Defendant had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

53. The Testim that was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was manufactured defectively in that said product left the hands of Defendant in a defective condition and was unreasonably dangerous to its intended users.

54. The Testim designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant reached its intended users in the same defective and unreasonably dangerous condition in which the Defendant's product was manufactured.

55. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff GORDON DANDURAND, in particular, and Defendant is therefore strictly liable for the injuries sustained by the Plaintiff.

56. The Plaintiff could not, by the exercise of reasonable care, discover the defective nature of using the Testim herein mentioned and perceived its danger.

57. The Testim designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate warnings or instructions as the Defendant knew or should have known that Testim created a risk of serious and dangerous side effects including but not limited to pain, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, and/or other severe and permanent health consequences.

58. The Testim designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate warnings and/or inadequate testing.

59. The Testim designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendant knew or should have known of the risks of serious side effects including but not limited to pain, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, and/or other severe and permanent health consequences.

60. By reason of the foregoing, the Defendant has become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of Testim.

61. Defendant's defective design, manufacturing defect, and inadequate warnings for Testim were acts that amount to willful, wanton, and/or reckless conduct by Defendant.

62. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks,

strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

63. As a result of the foregoing acts and omissions Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

64. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in an amount to be determined at trial.

THIRD CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

65. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

66. Defendant expressly warranted that Testim was safe and well accepted by users.

67. Testim does not conform to these express representations because it is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendant. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer, and/or is at increased risk to suffer severe and permanent personal injuries, harm and/or economic loss.

68. Plaintiff did rely on the express warranties of the Defendant herein.

69. Members of the medical community, including physicians and/or other healthcare professionals, relied upon the representations and warranties of the Defendant for use of Testim in recommending and/or dispensing it.

70. The Defendant herein breached the aforesaid express warranties, as its Testim was defective.

71. Defendant expressly represented to Plaintiff, and/or his physicians, healthcare providers that Testim was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other, non-defective testosterone products, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

72. Defendant knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Testim is not safe and fit for the use intended, and, in fact, produced serious injuries to the users that was not accurately identified and represented by Defendant.

73. By reason of the foregoing, Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

74. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

75. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in an amount to be determined at trial.

FOURTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTIES)

76. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

77. At all times herein mentioned, Defendant manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold testosterone products for the treatment of Low T.

78. At the time Defendant marketed, sold, and distributed Testim for use by Plaintiff, Defendant knew of the use for which Testim was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

79. Defendant impliedly represented and warranted to the users of Testim and/or their physicians, healthcare providers, and/or the FDA that Testim was safe and of merchantable quality and fit for the ordinary purpose for which said products were to be used.

80. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Testim was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

81. Plaintiff and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

82. Plaintiff and/or his physicians and/or healthcare professionals reasonably relied upon the skill and judgment of Defendant as to whether Testim was of merchantable quality and safe and fit for its intended use.

83. Testim was injected into the stream of commerce by the Defendant in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

84. The Defendant herein breached the aforesaid implied warranties, as Testim was not fit for its intended purposes and uses.

85. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

86. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

87. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in an amount to be determined at trial.

FIFTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

88. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

89. The Defendant falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff and/or the FDA, and/or the public in general, that Testim, had been tested and was found to be safe and/or effective for the treatment of Low T.

90. That representations made by Defendant were, in fact, false.

91. When said representations were made by Defendant, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

92. These representations were made by said Defendant with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase Testim, for treatment of Low T, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

93. At the time the aforesaid representations were made by the Defendant and, at the time the Plaintiff used Testim, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

94. In reliance upon said representations, the Plaintiff was induced to and did use Testim, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

95. Said Defendant knew and was aware or should have been aware that Testim had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

96. Defendant knew or should have known that Testim had a potential to, could, and would cause severe and grievous injury to the users of said products, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

97. Defendant brought Testim to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

98. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

99. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

100. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in an amount to be determined at trial.

SIXTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

101. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

102. At all times during the course of dealing between Defendant and Plaintiff and/or Plaintiff's healthcare providers, and/or the FDA, Defendant misrepresented the safety of Testim for their intended use.

103. Defendant knew or was reckless in not knowing that its representations were false.

104. In representations to Plaintiff and/or Plaintiff's healthcare providers and/or the FDA, Defendant fraudulently concealed and intentionally omitted the following material information:

a. That Testim was not as safe as other available testosterone replacement products;

b. That the risks of adverse events with Testim was higher than those with other available testosterone replacement products;

c. That the risks of adverse events with Testim was not adequately tested and/or known by Defendant;

d. Plaintiff was put at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish;

e. That patients needed to be monitored more regularly than normal while using Testim;

f. That Testim was manufactured, marketed, produced, and distributed negligently;

g. That Testim was manufactured, marketed, produced, and distributed defectively;

h. That Testim was manufactured, marketed, produced, and distributed improperly;

i. That Testim was designed negligently;

j. That Testim was designed defectively; and

k. That Testim was designed improperly.

105. Defendant was under a duty to disclose to Plaintiff and/or his physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Testim.

106. Defendant had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Testim, including the Plaintiff in particular.

107. Defendant's concealment and omissions of material facts concerning, *inter alia*, the safety of the use of Testim was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and/or his physicians, hospitals and/or healthcare providers into reliance, continued use of Testim, and actions thereon, and to cause them to purchase, recommend, and/or dispense Testim and/or use it.

108. Defendant knew that Plaintiff and/or his physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding Testim, as set forth herein.

109. Plaintiff, as well as his doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendant.

110. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

111. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses.

112. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in an amount to be determined at trial.

SEVENTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

113. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

114. Defendant had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and/or the public in general that Testim, had been tested and found to be safe and effective for its intended use as testosterone replacement therapy.

115. The representations made by Defendant were, in fact, false.

116. Defendant failed to exercise ordinary care in the representation of Testim, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of

said product into interstate commerce, in that Defendant negligently misrepresented Testim's high risk of unreasonable, dangerous side effects.

117. Defendant breached their duty in representing Testim's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and/or the public in general.

118. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

119. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

120. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in an amount to be determined at trial.

EIGHTH CAUSE OF ACTION
(FRAUD AND DECEIT)

121. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

122. Defendant conducted research and used Testim as part of its research.

123. As a result of Defendant's research and testing, or lack thereof, Defendant blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, his doctors, hospitals, healthcare professionals, and/or the FDA that Testim was safe for their intended use.

124. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

125. Defendant had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as their healthcare providers and/or the FDA.

126. The information distributed to the public, the FDA, and the Plaintiff by Defendant, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

127. The information distributed to the public, the FDA, and the Plaintiff by Defendant intentionally included representations that Defendant's Testim was safe for its intended use.

128. The information distributed to the public, the FDA, and the Plaintiff by Defendant intentionally included representations that Defendant's Testim carried the same risks, hazards, and/or dangers as other testosterone replacement products.

129. The information distributed to the public, the FDA, and the Plaintiff by Defendant intentionally included false representations that Testim was not injurious to the health and/or safety of its intended users.

130. These representations were all false and misleading.

131. Upon information and belief, Defendant intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that Testim was not safe for use as testosterone replacement therapy.

132. Defendant intentionally made material representations to the FDA and/or the public, including the medical profession, and the Plaintiff regarding the safety of testosterone products, specifically but not limited to Testim not having dangerous and serious health and/or safety concerns.

133. Defendant intentionally made material representations to the FDA and/or the public in general, including the medical profession, and the Plaintiff regarding the safety of Testim.

134. That it was the purpose of Defendant in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff to falsely ensure the quality and fitness for use of Testim and induce the public, and/or the Plaintiff to purchase, request, dispense, recommend, implant and/or continue to use testosterone products.

135. Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Testim was fit and safe for use as testosterone replacement therapy.

136. Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Testim was fit and safe for use as testosterone replacement therapy and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other available testosterone replacement therapy.

137. That Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Testim did not present serious health and/or safety risks.

138. That Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Testim did not present health and/or safety risks greater than other available testosterone replacement products.

139. That these representations were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

140. That these representations and others, made by Defendant, were made with the intention of deceiving and defrauding the Plaintiff, his healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or his healthcare professionals to rely upon misrepresentations and caused the Plaintiff and/or his healthcare professionals to purchase, use, rely on, request, dispense, and/or recommend Testim.

141. That Defendant, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of testosterone products to the public at large, including the Plaintiff, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

142. That Defendant willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Testim by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Testim.

143. That Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving

and lulling the Plaintiff, as well as his healthcare professionals, into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Testim and/or that his healthcare providers would dispense, prescribe and/or recommend the same.

144. Defendant, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as his healthcare professionals would rely upon the information being disseminated.

145. Defendant utilized direct to consumer adverting to market, promote, and/or advertise Testim.

146. That the Plaintiff and/or his healthcare professionals did in fact rely on and believe the Defendant's representations to be true at the time they were made and relied upon the representations as well as its superior knowledge of Testim and was thereby induced to purchase, use and rely on Defendant's testosterone products.

147. That at the time the representations were made, the Plaintiff and/or his healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Testim.

148. That the Plaintiff did not discover the dangerous and serious health and/or safety concerns and the false representations of Defendant nor could the Plaintiff, with reasonable diligence, have discovered the true facts.

149. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Testim, Plaintiff would not have purchased, used and/or relied on Defendant's Testim.

150. That the Defendant's aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

151. By reason of the foregoing Plaintiff has experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

152. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

153. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in an amount to be determined at trial.

NINTH CAUSE OF ACTION
(NEGLIGENT MARKETING)

154. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

155. Defendant had a duty to exercise reasonable care in the marketing of Testim. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events.

156. Defendant failed to exercise reasonable care in the marketing of Testim in that

they knew or should have known that this product could cause significant bodily harm or death and was not safe for use by consumers including Plaintiff.

157. Defendant failed to exercise ordinary care in the initial design of Testim, in the failure to investigate information about the risks Testim poses, and in their decision to continue to sell Testim despite those unreasonable risks.

158. At all relevant times, it was foreseeable to Defendant that consumers like Plaintiff would suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

159. As a direct and proximate result of Defendant's negligence, Plaintiff has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

160. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in an amount to be determined at trial.

TENTH CAUSE OF ACTION
(NEGLIGENT DESIGN)

161. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

162. Defendant had a duty to exercise reasonable care in the design of Testim. In particular, it had a duty to assure that its products did not pose an unreasonable risk of bodily harm and adverse events.

163. Defendants failed to exercise reasonable care in the design of Testim in that it knew or should have known that this product could cause significant bodily harm or death and was not safe for use by consumers, including Plaintiff.

164. At all relevant times, it was foreseeable to Defendant that consumers like Plaintiff would suffer injury as a result of Defendant's failure to exercise ordinary care as described

above.

165. As a direct and proximate result of Defendant's negligence, Plaintiff has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

166. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in an amount to be determined at trial.

ELEVENTH CAUSE OF ACTION
(LOSS OF CONSORTIUM)

167. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

168. Plaintiff MARGARET DANDURAND, was and is the lawful spouse of Plaintiff GORDON DANDURAND, and as such, was and is entitled to the comfort, enjoyment, society and services of her spouse.

169. As a direct and proximate result of the foregoing, Plaintiff MARGARET DANDURAND, was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff GORDON DANDURAND, and has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

170. For the reasons set forth herein, Plaintiff MARGARET DANDURAND suffered and will continue to suffer the loss of her loved one's support, companionship, services, society, love and affection.

171. As a result of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendant on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case will be transferred for trial;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendant and deter future similar conduct;

4. Awarding Plaintiffs reasonable attorney's fees;

5. Awarding Plaintiffs the costs of these proceedings; and

6. Such other and further relief as this Court deems just and proper.

JURY DEMANDED

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs hereby demand trial by jury as to all issues.

Dated: August 28, 2014

/s/ *Gregory S. Spizer*
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